

comments that yielded improvements to our data collection instrument, and we are therefore submitting a revised data collection form for emergency clearance.

The definition of subsidized employment used for this collection is the same as the definition for the TANF program in general, given in 45 CFR 261.2(c) and (d). This information will help the agency as well as the public better understand how jurisdictions are

using the money they are awarded through the Emergency Fund.

A voluntary information collection relating to the number of individuals in subsidized employment will serve several purposes.

This information will demonstrate the impact of the program, help ACF to evaluate the effectiveness of this initiative, and provide information to aide in the transparency and accountability of jurisdictions receiving

Recovery Act funds. This information will also allow the Administration to publicly communicate the impact and achievements of the program, and make future policy decisions on the basis of such knowledge.

Respondents: State, territory, and tribal agencies administering the Temporary Assistance for Needy Families (TANF) Program that have received TANF Emergency Funds.

Instrument	Number of respondents (jurisdictions)	Number of responses per respondent	Average burden hours per response	Total burden hours
Subsidized Employment Report OFA-200	74	1	24	1,776

Estimated Total Annual Burden Hours: We estimate the annualized cost of the hour burden to be \$159,840. This figure is based on an estimated average hourly cost of \$90 (including fringe benefits, overhead, and general and administrative costs) for the jurisdiction staff performing the work multiplied by the estimated 1,776 burden hours, calculated based on 74 jurisdictions applying for and receiving TANF Emergency Funds (all States and Territories, plus an estimated 20 tribes) If the TANF Emergency Fund is extended and jurisdictions report in FY 2011, the jurisdiction would submit four additional responses and the total burden hours for FY 2011 would be 7,104.

Additional Information: ACF is requesting that OMB grant a 180-day approval for this information collection under procedures for emergency processing by September 13, 2010. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Reports Clearance Officer, Robert Saris at (202) 690-7275.

Comments about the information collection described above should be directed to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503; FAX: (202) 395-7285; e-mail: oirasubmission@ornb.eop.gov.

Dated: August 18, 2010.

Robert Sargis,
Reports Clearance Officer.

[FR Doc. 2010-21203 Filed 8-26-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Assessing the Long-Term Impacts of the John E. Fogarty International Center's Research and Training Programs

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the John E. Fogarty International Center, the National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 27, 2010 (volume 75, number 102, page 29763) and allowed 60 days for public comment. One comment was received from a member of the public. The purpose of this notice is to allow an additional 30 days for public comment.

Proposed Collection: Title: Assessing the Long-Term Impacts of the John E. Fogarty International Center's Research and Training Programs. *Type of Information Collection Request:* New collection. *Need and Use of Information Collection:* This study will inform investment decisions and strategies employed by the Fogarty International Center for the purpose of strengthening biomedical research capacity in low and middle income countries. The primary objective of the study is to develop detailed case studies of the long-term impacts of Fogarty's research and training programs on educational institutions located in low and middle income countries. The findings will provide valuable information concerning return on the Center's investments over the past twenty years and effective strategies for promoting

research capacity development in the future. *Frequency of Response:* Once. *Affected Public:* Individuals. *Type of Respondents:* Current and former NIH grantees; Current and former NIH trainees in countries of interest; Leaders and administrators at institutions of interest; Policy-makers and scientific leaders in countries of interest. The annual reporting burden is as follows:

Estimated Number of Respondents: 210 per year. *Estimated Number of Responses per Respondent:* 1. *Average Burden Hours per Response:* 1. *Estimated Total Annual Burden Hours Requested:* 290. The annualized cost to respondents is estimated at: \$4,841. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of

Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Linda Kupfer, Fogarty International Center, National Institutes of Health, 16 Center Drive, Bethesda, MD 20892, or call non-toll-free number 301-496-3288, or e-mail your request, including your address to: *Linda.Kupfer@nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: August 23, 2010.

Timothy J. Tosten,

Executive Officer, John E. Fogarty International Center, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0433]

Draft Guidance for Industry on Acute Bacterial Skin and Skin Structure Infections: Developing Drugs for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Acute Bacterial Skin and Skin Structure Infections: Developing Drugs for Treatment." The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drugs for the treatment of acute bacterial skin and skin structure infections (ABSSSI), impetigo, and minor cutaneous abscesses. FDA's thinking in this area has evolved in recent years, and this draft guidance, when finalized, will inform sponsors of the changes in the definitions of ABSSSI and the recommendations for clinical drug development.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments

on the draft guidance by November 26, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6244, Silver Spring, MD 20993-0002, 301-796-1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Acute Bacterial Skin and Skin Structure Infections: Developing Drugs for Treatment." The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drugs for the treatment of ABSSSI, impetigo, and minor cutaneous abscesses. This guidance revises the draft guidance regarding uncomplicated and complicated skin and skin structure infections published in 1998. The guidance also addresses the clinical development of new drugs to treat drug-resistant bacterial pathogens implicated in ABSSSI, such as methicillin-resistant *Staphylococcus aureus*.

The definitions of ABSSSI and the designs of ABSSSI clinical trials were discussed at a meeting of the Anti-Infective Drugs Advisory Committee on November 18, 2008. In addition, other advisory committee meetings have focused on the development of specific drugs for this indication. As a result of these public discussions, as well as review of applications at FDA, the agency's thinking in this area has evolved in recent years and this draft guidance informs sponsors of the changes in our recommendations. Specifically, the guidance defines the clinical disease entities and provides a justification for a noninferiority margin for the design of active-controlled

clinical trials that can be used to provide evidence of efficacy for the treatment of ABSSSI. The guidance describes a new responder efficacy endpoint for noninferiority trials that is based on the historical studies used to justify the noninferiority margin. Currently, there are ongoing efforts in the scientific community to develop and evaluate new efficacy endpoints for ABSSSI. The guidance also defines the clinical disease entities of skin infections for which a superiority trial is recommended.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on developing drugs for the treatment of ABSSSI. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014 and the collections of information in 21 CFR part 314 have been approved under OMB control number 0910-0001.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.